Registration Decision RD2016-18

# Hydrogen Peroxide

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607 D
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

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## Registration Decision Statement[1] for Hydrogen Peroxide

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Interox M-70 Hydrogen Peroxide, Interox CPMC-50 and Interox Paramove 50, containing the technical grade active ingredient hydrogen peroxide, for the treatment of sea lice on Atlantic salmon reared in marine aquaculture sites.

This decision is consistent with the Proposed Registration Decision PRD2014-11, *Hydrogen Peroxide,* which contains a detailed evaluation of the information submitted in support of this registration. The evaluation found that, under the approved conditions of use, the products have value and do not present an unacceptable risk to human health or the environment. See Appendix I for a summary of comments received during the consultation process as well as the PMRA's response to these comments.

## Other Information

The relevant test data on which the decision is based (as referenced in PRD2014-11, *Hydrogen Peroxide)* are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[2] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticide and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service

[1] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act.*

[2] As per subsection 35(1) of the *Pest Control Products Act.*

# Appendix I Comments and Responses

**Comment**

Because hydrogen peroxide is a relatively benign product that poses little or no risk to salmon, the marine environment, non-target species, or human health, we would like to suggest that PMRA consider allowing up to six (6) treatments per year. Based on the data from one of the industry's worst years for sea lice management, it would have been helpful if the industry had been able to perform one additional treatment that year. This would give farmers some flexibility since the optimal use of the product is also based on water temperatures and higher water temperatures would mean that a lower dose of the product would be used.

**Response**

The PMRA does not expect that increasing the number of applications per year for Interox Paramove 50 by one application would increase the human health risks to workers or bystanders or would result in an increase in risk to non-target organisms. There is also no objection to an increase from a value perspective. Therefore, the PMRA has no objection to increasing the maximum number of applications per year from five (5) to six (6).

**Comment**

We realize that diver safety is very important. We agree that divers should not dive within wells or net pens for at least one hour post treatment. However, this should be stated as one hour following a flush of a wellboat or following the removal of a skirt or tarpaulin on a net pen. The term "tidal cycle" should not be used because a tidal cycle in New Brunswick has a distinctly different meaning than other regions in Canada such as Newfoundland and Labrador. A tidal cycle can well exceed the one hour time frame depending on the time of day of the treatment.

**Response**

Neither the label for Interox Paramove 50 nor PRD2014-11, *Hydrogen Peroxide,* includes the term, "tidal cycle" in reference to divers performing tasks in wellboat wells or net pens (sea cages). Also, the label does not include a restricted entry interval specifying when divers should or should not enter the sea cages. In section 3.2.3 of PRD2014-11, *Hydrogen Peroxide, Post-Application Exposure and Risk*, it is noted that divers only enter sea cages at least an hour after treatments are finished, the tarpaulins are removed, and after tidal flushing occurs. This is based on information included in the submission for Interox Paramove 50 from the applicant. Also, based on the information submitted to the PMRA by the applicant, divers do not perform tasks in wellboat wells.

Divers normally wear dry suits and masks when entering sea cages, the maximum concentrations of hydrogen peroxide used to treat sea cages are very low (0.18%) compared to other applications (for example, 3% solution used as an antiseptic to treat skin abrasions and cuts), and after tarpaulin removal, the concentrations in the sea cages are expected to decrease rapidly due to dispersion and degradation. Consequently, the PMRA is not proposing any modifications to the label with respect to sea cage re-entry intervals for divers at this time.

**Comment**

We are not clear on the use of the term "Level of Concern" (Page 15 of the PRD2014-11, *Hydrogen Peroxide*). We would like additional information on the definition and how rankings are determined. Overall, our concerns are the lack of information on the long term cumulative impact of the use of hydrogen peroxide on non-target species, especially juvenile lobster and copepods.

**Response**

Health Canada's Pest Management Regulatory Agency (PMRA) is mandated to prevent unacceptable risks to people and the environment from the use of pesticides. The PMRA understands the concerns associated with the use of pest control products and their potential for impacts on non-target organisms, including species such as juvenile lobster and copepods and considers these species in the review process.

The "Level of Concern" (LOC) is a threshold value used to identify whether or not the application of a pest control product has the potential to cause a defined detrimental effect (such as reduced body weight or mortality) on a non-target organism. When the level of concern is not exceeded, the use of the pesticide product is expected to pose a negligible risk to populations of the specified non-target organism. The PMRA does not have a ranking for the level of concern as it is a fixed value based on a predefined group of non-target organisms.

The PMRA uses modern scientific assessment techniques to assess human and environmental health risks when evaluating and re-evaluating pest control products. The PMRA has assessed the long term cumulative impacts of the use of hydrogen peroxide on non-target species by reviewing a large number of scientific studies on: what happens to hydrogen peroxide when it enters the environment as well as the effects of hydrogen peroxide on non-target species, including juvenile lobster and copepods. Based on these studies, the PMRA has determined that the long term use of hydrogen peroxide, taking cumulative impacts into consideration, is expected to not pose risks of concern to non-target marine organisms such as mammals, crustaceans, birds, adult lobsters, lobster larvae, copepods or fish.

The PMRA's risk assessment approach and scientific information requirements are comparable to those of other countries around the world such as the United States, the United Kingdom, Australia and others. Much of the scientific information which the PMRA used in order to evaluate the risk to non-target species, such as juvenile lobster and copepods, from the use of hydrogen peroxide was conducted by experts in marine biology and marine oceanography from the Department of Fisheries and Oceans and Environment Canada.

To ensure registered products continue to meet the most modern health and environmental standards, hydrogen peroxide will be reassessed on a cyclical basis at least every 15 years through a re-evaluation review process.

All pesticides are tested and evaluated for safety before being registered for use by Canadians. To continue to monitor for safety after they are registered, Health Canada collects pesticide incident reports from Canadians. For more information on Health Canada's pesticide incident reporting program, please visit http://www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/incident/index-eng.php.

**Comment**

Currently there is no physical restriction to prevent anyone from entering a salmon site. When treatments are underway, flagging is limited if done at all. Our area is frequented by leisure vessels from other parts of Canada and the United States who may not be aware of the type of activity being conducted and the risks associated with this chemical. We would implore the Department to require the flags to carry the same symbol as is used on the packaging for the chemical which is universally understood to mean that there is a hazard in the vicinity.

**Response**

The label for Interox Paramove 50 provides directions on restricting entry into fish farm areas until treatments are completed and not permitting recreational activities in treated water near fish farm areas until tidal flushing occurs. In general, requirements for signage or flags at sites of application for pesticides are associated with pesticide use permit requirements managed by provincial authorities. It is recommended that the relevant provincial authorities be contacted for questions about requirements for signage or flags at the sites where Interox Paramove 50 is to be applied.

**Comment**

Concerns were raised that the requirement for workers to wear a respirator to reduce inhalation exposure is not practical and may hinder a person's visibility, hearing and communication; and increase the potential for other risk events such as "fall from height" and "fall in to water" to occur.

**Response**

The active ingredient in Interox Paramove 50, hydrogen peroxide, is moderately acutely toxic via inhalation and is corrosive to the eyes and skin. Consistent with other non-conventional pesticides, the PMRA assessment of Interox Paramove 50 used a qualitative approach to mitigate the risks from hydrogen peroxide that included requirements for personal protective equipment (PPE) on the label, such as the use of a NIOSH-approved respirator. Label requirements for respirator use during tarpaulin applications of Interox Paramove 50 are also consistent with labelling used for previous emergency registrations for the product. Given that detailed information on exposure control measures of the types described in the comments above was not included in the submission for Interox Paramove 50, the PMRA is not recommending any modifications to the respirator requirements on the label at this time. However, the PMRA would be willing to consider a future follow-up submission that includes additional information on exposure control measures to support modifications to the respirator requirements on the label.